Action Information

Action: Notice

Title: Registration Review Interim Decision; Notice of Availability

SAN:/Tier Level: N/A; OMB Significance: N/A; FRL: [9952 - 83]; RCS: [16P - 0238].

Purpose: The purpose of this FR notice is to notify the public of the availability of interim decisions. The registrants rely on these documents to make amendments to their labels, if applicable. These documents represent the completion of Registration Review for a specific pesticide.

Background: These FR notices are a core component of the routine and day-to-day aspects of the licensing program for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In particular, this notice supports the activities related to the Registration Review Program mandate in FIFRA – See attached program overview.

Ex. 5 - Deliberative Process

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Registration Review Related Federal Register Documents – An Overview

- Statutory mandate – FIFRA Section 3(g) requires the Agency to review each registered pesticide every 15 years to ensure the products continue to meet the FIFRA standard.
- Scope -- The current registration review program has 724 "cases" encompassing 1,140 pesticide active ingredients (A.I.).
- Statutory Deadline – EPA must complete review of ALL cases/A.I. by 10/1/2022; 40 CFR §155.44 establishes Agency's requirement to set an annual schedule for registration review (https://www.epa.gov/pesticide-reevaluation/registration-review-schedules). These deliverables are part of the Annual Performance Measures and Goals and the Agency must document at mid-year and end of year if they have met these measures and goals.
- Timing – Due to the volume of chemicals reviewed by the program, these FRs need to be released in a timely manner as each registration review case is on a schedule to meet the ultimate deadline of 2022. Each step of the process outlined below is sensitive to delays because the domino effect quickly leads to backlogs and delays for the next step of the registration review process.
- Registration review procedures are laid out in 40 CFR Part 155, Subpart C and they include publishing Federal Register Notice to increase transparency and facilitate public participation for the following documents:
    - **Final work plan** (*purpose: informational only*) -- The document finalizes and responds to comments on the Preliminary Work Plan, which summarizes what information EPA has on the pesticide, and the anticipated path forward such as the schedule for data call-ins, draft risk assessments, and decision documents. All cases have completed the Preliminary Work Plan step and all data call-ins have been cleared by OMB.
    - **Draft risk assessment** (*purpose: solicitation of public comments for 60 days or longer*) – The assessments (Human Health and Ecological) contain updates since the last registration decision and are typically released for 60-day public comment periods. These risk assessments undergo internal programmatic review. No decisions are tied to these risk assessments. Groups of draft risk assessments are released on a quarterly basis.
    - **Proposed decision or proposed interim decision** (*purpose: solicitation of public comments for 60 days or longer*) – The document proposes risk management decisions based on revised human health and ecological risk assessments that incorporate comments received during the risk assessment comment period. In many cases, the proposed decisions are based on discussions with registrants, grower groups, USDA, and other stakeholders. These proposed decisions undergo internal programmatic review. Groups of PIDs are released on a quarterly basis.
    - **Interim or Final Decisions** (*purpose: informational only*) --The document finalizes and responds to comments on the proposed decisions or proposed interim decisions. The registrants rely on the document to make amendments to their labels, if applicable. These documents represent the completion of Registration Review for a specific pesticide. Groups of decisions are released on a quarterly basis.
- Additional FRNs for the program include the following:
    - **Comment Period Extensions/Reopening of Comment Period** – These type of FRs are administrative in nature. Comment periods on risk assessments and decision documents are often extended at the request of stakeholders.
    - **Voluntary cancelation of products initiated by the registrants** -- In accordance with FIFRA section 6(f)(1), when companies voluntarily cancel their product registration, EPA issue a notice of receipt of requests through the Federal Register Notice process to inform the public.
    - **Annual Performance Measures and Goals** – this documents reports the progress of the registration review program and whether it has met its annual projected commitment.
- Each document stated above is a critical path for the subsequent document in order for the program to meet

the statutory mandate of completing the 724 registration review “cases” that include approximately 1,140 pesticide active ingredients by year 2022.